§ 241

TRANSFER OF APPROPRIATED FUNDS


SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART A—RESEARCH AND INVESTIGATIONS

§ 241. Research and investigations generally

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2393 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains—

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed,

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subpara-
graph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and
(D) a description of (i) each request received during the year involved—
(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or
(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

(e) Preterm labor and delivery and infant mortality

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery and infant mortality.


AMENDMENTS


1988—Subsec. (d). Pub. L. 100–679 redesignated concluding provisions of subsec. (a) of section 229a of this title as subsec. (b) of this section, substituted “bio-medical, behavioral, clinical, or other research” for “research on mental health, including”, and substituted “drugs)” for “drugs’’.

1986—Subsec. (a)(3). Pub. L. 99–570 struck out “or, in the case of mental health projects, by the National Advisory Mental Health Council;” after “Department supporting such projects,” and struck out “or the National Advisory Mental Health Council” after “appropriate entity of the Department”.


1985—Subsec. (a)(3). Pub. L. 99–158, §3(a)(5)(A), substituted “as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council;” for “such projects,” and struck out “or the National Advisory Mental Health Council” after “appropriate entity of the Department”.


1983—Pub. L. 92–423 redesignated concluding provisions of subsec. (a) of section 229a of this title as subsec. (b) of this section, substituted “biomedical, behavioral, clinical, or other research” for “research on mental health, including”, and substituted “drugs)” for “drugs’’.

1982—Pub. L. 97–35 subtracted “or, in the case of mental health projects, by the National Advisory Mental Health Council;” after “Department supporting such projects,” and struck out “or the National Advisory Mental Health Council” after “appropriate entity of the Department”.


Subsec. (a)(8), Pub. L. 99-158, §3(a)(5)(B), substituted "recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers" for "recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems".

1978—Pub. L. 95-622 designated existing provisions as subsec. (a), redesignated former pars. (a) to (h) as (1) to (8), respectively, substituted "Secretary" for "Surgeon General" wherever appearing, and inserted following par. (8) provisions relating to authority of Secretary to make available to individuals and entities substances and living organisms, and added subsec. (b).

1976—Subsecs. (c), (h). Pub. L. 94-278 substituted "heart, blood vessel, lung, and blood diseases and blood resources" for "heart diseases" and "National Heart, Lung and Blood Advisory Council" for "National Heart and Lung Advisory Council".

1974—Subsec. (c), Pub. L. 93-348, §104(a)(1), redesignated subsec. (d) as (c) and substituted "research projects" for "research or research training projects" in two places, "general support of their research" for "general support of their research and research training programs" and "research grants-in-aid" for "research and research training program grants-in-aid". Former subsec. (c), authorizing Surgeon General to establish and maintain research fellowships in the Public Health Service with such stipends and allowances, in including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad, was struck out.

Subsec. (d), Pub. L. 93-348, §104(a)(1)(C), redesignated subsec. (e) as (d).

1967—Pub. L. 90-174 substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(7), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (b)(1), (3), and (4)(D)(1), (II), pursuant to section 506(b) of Pub. L. 96-88 which is classified to section 500(b) of Title 20, Education.

Subsec. (g). Pub. L. 90-322 substituted "mental health, including research on the use and effect of alcohol and other psychoactive drugs" for "the use and effect of drugs" in former concluding provisions of section 242a(a) of this title. See 1988 Amendment note above.

Subsecs. (e), (f). Pub. L. 93-348, §104(a)(1)(C), redesignated subsecs. (f) and (g) as (e) and (f), respectively. Former subsec. (e) redesignated (d).

Subsec. (g). Pub. L. 93-352 struck out "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years" after "Enter into contracts". Pub. L. 93-348 substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(7), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (b)(1), (3), and (4)(D)(1), (II), pursuant to section 506(b) of Pub. L. 96-88 which is classified to section 500(b) of Title 20, Education.

Subsec. (h). Pub. L. 93-348, §104(a)(1)(C), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f), redesignated subsec. (h) and (i) as (g) and (h), respectively. 1972—Subsecs. (d), (i). Pub. L. 92-423 substituted "National Heart and Lung Advisory Council" for "National Advisory Heart Council".

1971—Subsec. (d), (i). Pub. L. 92-218 substituted "National Cancer Advisory Board" for "National Advisory Cancer Council".


Subsec. (h). Pub. L. 91-515 substituted "eight" for "five" succeeding fiscal years.


1965—Pub. L. 89-788 inserted "‘research training’ in two places.

1960—Subsec. (d). Pub. L. 86-788 authorized the Surgeon General, upon recommendation of the National Advisory Health Council, to make grants to public or non-profit universities, laboratories, or other institutions to support research and research training programs, and to make available for such research and research training programs, up to 15 percent of amounts provided for research grants through the appropriations for the National Institutes of Health.

1956—Subsecs. (g), (h). Act July 3, 1956, added subsec. (g) and redesignated former subsec. (h) as (g).

1948—Subsec. (d). Acts June 16, 1948, §4(e), and June 24, 1948, §4(e), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

Subsec. (d). Act June 25, 1948, continued in basic legislation the authority to purchase penicillin and other antibiotic compounds for use in research projects.

Subsec. (g). Acts June 16, 1948, §4(f), and June 24, 1948, §4(f), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

1946—Subsec. (d). Act July 3, 1946, made the National Advisory Mental Health Council the body to make recommendations to the Surgeon General on awarding of grants-in-aid for research projects with respect to mental health.

Subsec. (g). Act July 3, 1946, gave National Advisory Health Council the right to make recommendations to carry out purposes of this section.
shall do the following:

**FEMALE GENITAL MUTILATION**


“(a) Congress finds that—

(1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and

(2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved.

“(b) The Secretary of Health and Human Services shall—

(1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation.

(2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice.

(3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation. Such recommendations shall be disseminated to such schools.

(4) For purposes of this section the term ‘female genital mutilation’ means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major.

“(d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act [Apr. 26, 1996].”

**SENTINEL DISEASE CONCEPT STUDY**

Section 1910 of Pub. L. 101–43 directed Secretary of Health and Human Services, in cooperation with Agen-

**ANALYSIS OF THYROID CANCER: CREATION AND PUBLICATION OF RADIOEPIDEMIOLOGICAL TABLES**


“(a) In carrying out section 301 of the Public Health Service Act [this section], the Secretary of Health and Human Services shall—

(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout; and

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests.

“(b)(1) Within one year after the date of enactment of this Act [Jan. 4, 1983], the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary,
after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

“(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish—

“(A) a formula of the formulas that yielded the probabilities of causation listed in such tables. Such formula shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

“(B) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise.

Section 1. Policy. Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.

For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Pres.

The Presidential statement of governmental policy, August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as a statement of governmental policy.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 5. Revocations. (a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall be revoked.

BARACK OBAMA.

GUIDELINES FOR HUMAN STEM CELL RESEARCH

Memorandum of the Heads of Executive Departments and Agencies

As outlined in Executive Order 13505 of March 9, 2009, my Administration is committed to supporting and conducting ethically responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law. Pursuant to that order, the National Institutes of Health (NIH) published final “National Institutes of Health Guidelines for Human Stem Cell Research” (Guidelines), effective July 7, 2009. These Guidelines apply to the expenditure of NIH funds for research using human embryonic stem cells and certain uses of human induced pluripotent stem cells. The Guidelines are based on the principles that responsible research with human embryonic stem cells has the potential to improve our understanding of human biology and aid in the discovery of new ways to prevent and treat illness, and that individuals donating embryos for research purposes should do so freely, with voluntary and informed consent. These Guidelines will ensure that NIH-funded research adheres to the highest ethical standards.

In order to ensure that all federally funded human stem cell research is conducted according to these same principles and to promote a uniform Federal policy across the executive branch, I hereby direct the heads of executive departments and agencies that support and conduct stem cell research to adopt these Guidelines, to the fullest extent practicable by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

The President of the United States, by virtue of the authority vested in me as President of the United States, by the Constitution and the laws of the United States of America, is hereby ordered as follows:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Sec. 2. Research. The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

Sec. 3. Guidance. Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order. The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

Sec. 4. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof;

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 5. Revocations. (a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall be revoked.

BARACK OBAMA.
§ 242. Studies and investigations on use and misuse of narcotic drugs and other drugs; annual report to Attorney General; cooperation with States

(a) In carrying out the purposes of section 241 of this title with respect to drugs the use or misuse of which might result in drug abuse or dependence, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act [21 U.S.C. 801 et seq.] and Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.], together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts.

(b) The Surgeon General shall cooperate with States for the purpose of aiding them to solve their narcotic drug problems and shall give authorized representatives of the States the benefit of his experience in the care, treatment, and rehabilitation of narcotic addicts to the end that each State may be encouraged to provide adequate facilities and methods for the care and treatment of its narcotic addicts.


REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (a), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1282, as amended, which is classified principally to subchapter I (§801 et seq.) of chapter 13 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 801 of Title 21. Food and Drugs.

The Controlled Substances Import and Export Act, referred to in subsec. (a), is title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1283, as amended, which is classified principally to subchapter II (§851 et seq.) of chapter 13 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 801 of Title 21 and Tables.

AMENDMENTS

1970—Subsec. (a). Pub. L. 91–513 inserted references to drug dependency, drugs other than narcotic drugs, and substances subject to control under the Controlled Substances Act and the Controlled Substances Import and Export Act, substituted the first day of April of each year for the first day of September of each year as the date by which the study results must be submitted, substituted the Attorney General for the Secretary of the Treasury as the officer to whom the report is to be submitted, and struck out references to the Narcotic Drugs Import and Export Act.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of Title 21, Food and Drugs.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of Title 21, Food and Drugs.

TRANSFER OF FUNCTIONS


MARIHUANA AND HEALTH REPORTING


§ 242b. General authority respecting research, evaluations, and demonstrations in health statistics, health services, and health care technology

(a) Scope of activities

The Secretary may, through the Agency for Healthcare Research and Quality or the National Center for Health Statistics, or using Ruth L. Kirschstein National Research Service Awards or other appropriate authorities, undertake and support training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evalu-